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Lisa Marie Sternke PhD(c), MSN, RN
Medical University of South Carolina, bassett@musc.edu

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Ethical Considerations of Nonmedical Preconception Gender Selection Research

Lisa Marie Sternke, PhD(c), MSN, RN

Medical University of South Carolina

Acknowledgement: Dr. Susan C. Benedict, DSN, RN, CRNA, FAAN

Abstract

Technological advances in reproductive science now afford prospective parents the ability to potentially choose the gender of their infant prior to conception; however, the bioethical considerations of preconception gender selection (PGS) research remain an ongoing debate in the scientific community. Opponents of PGS research argue it is unethical as it has the potential to cause a sex ratio imbalance, its availability is restricted to those with financial means, it promotes gender discrimination, and it may lead to further genetic discrimination based on desired traits (eugenics). Proponents of PGS research argue it is a parental right to choose the sex of a child, it could reduce atrocities toward unwanted children and the number of abortions, and it could assist in family balancing. Based on eleven bioethical concepts, it appears researchers may be unethically capitalizing on the emotional vulnerability of prospective parents in order to further genetic research into PGS for nonmedical reasons.

Ethical Considerations of Nonmedical Preconception Gender Selection Research

Introduction

Vulnerability is defined as “being susceptible to harm or neglect” and “to be in a position of being hurt or ignored” (Aday, 2001). Infertile couples seeking to have children are a vulnerable population as they are often desperate to have a child but lack the biological ability (The President's Council on Bioethics, 2004). A reasonable fear is they could be victims of potential exploitation for the purpose of both financial gain and scientific knowledge; therefore, they are in a position to be hurt and harmed. Fertile couples who have the known potential to pass on a fatal or debilitating hereditary condition to their offspring based on its gender, and are desperate to have a “normal” child, are also considered vulnerable for the same reason. Pre-implantation genetic diagnosis (PGD) affords these couples the ability to determine sex-linked disease markers in embryos and choose the embryo gender which would least likely be affected.

The process of PGD generated current research regarding preconception gender selection (PGS), and is allowing parents to attempt choosing child gender prior to conception regardless of genetic disease markers. The lack of regulation in the reproductive research field makes these couples vulnerable, especially financially as these services are quite expensive and basically experimental (ACOG Committee on Ethics, 2007; Center for Genetics and Society, 2006). Vulnerable populations can also be defined as those whose autonomy is diminished (Ludbrook, Clemens, Munson, & Scannell, 2005), and in the cases of couples hoping to have a specific gender child via PGS, autonomic choice ability may be reduced by a singular desire for a specific gender child. Since technological advances in reproductive science now afford prospective parents the potential ability to choose the gender of their infant prior to conception, new issues in protecting research participants arise.

MicroSort[®], an X-Y sperm sorting technology, is currently undergoing clinical trials at the Genetics and IVF Institute. The genetic research trials at MicroSort[®], however, have extended beyond the original research objective and now include the prospects of gender choice based upon parental preference alone, specifically by offering it as a method to balance families (Genetics and IVF Institute, 2006). Genetic research into gender selection has therefore slipped into the realm of research for nonmedical purposes. MicroSort[®]'s success rates so far present a frightening view of what may be to come in reproductive decision-making.

Statement of the Problem

Trying to influence the gender of a child preconception has been a common practice throughout history. Even Aristotle and Plato had suggestions on how to conceive a child of the desired gender (Dahl, 2003). Though the concept of PGS itself is not new, actual genetic research into successful sex selection for nonmedical purposes is, which raises an important question: Is it ethical to conduct genetic research specifically for the nonmedical purpose of advancement of PGS to satisfy parental preference? Based on the seven ethical requirements of bioethical research presented by this research, it is not (Emanuel, Wendler, & Grady, 2000).

Review of the Literature

Genetic research into PGS was intended to address the incidence of sex-linked disease in offspring (ACOG Committee on Ethics, 2007). By determining the genetic disease traits of parents, medical professionals could assess disease risks to potential offspring, and eventually offer the option of PGS in order to avoid having a specific-gender child suffer with a life-threatening or debilitating medical condition (Hollingsworth, 2005). Original PGS occurred through PGD, which involved the destruction of embryos based on disease characteristics and

therefore gender (an entirely different ethical argument) (Meseguer, Garrido, Remohi, Simon, & Pellicer, 2002; Robertson, 2001).

The MicroSort[®] sperm sorting process utilizes flow cytometric separation to determine whether a sperm has an X or a Y chromosome attached. When used in conjunction with intra-uterine insemination (IUI), in-vitro fertilization (IVF), or IVF and intracytoplasmic sperm injection (ICSI) together, it can increase the chances of having a gender-specific child. Results so far indicate the MicroSort[®] process increases X-bearing sperm load to 88%, resulting in a 92% success rate of female infant birth. It increases Y-bearing sperm load to 73%, resulting in an 81% success rate of male infant birth (Genetics and IVF Institute, 2006). Its significance is it does not involve the destruction of embryos pre-implantation.

There are several reasons PGS is considered by prospective parents, the primary medical reason being to reduce the risk of having a child with a sex-linked genetic disorder, i.e. choosing the sex with the least likely chance of being affected (ACOG Committee on Ethics, 2007; Robertson, 2003; The President's Council on Bioethics, 2004). As one example, the ACOG Committee on Ethics (2007) reports half of male sons born to a woman carrying the hemophilia gene will have hemophilia, and that “by identifying the sex of the pre-implantation embryo or fetus, a woman can learn whether or not the 50% risk of hemophilia applies, and she can receive appropriate prenatal counseling” (p. 475). Hemophilia is only one example, however. In consideration of other familial genetic diseases, PGS would be a valid parental consideration.

Parents may also have cultural, personal, or economic reasons to preselect a baby's gender (Chan, et al., 2002; Farrell, 2002; Mori & Watanabe, 2002; Oomman & Ganatra, 2002; Schenker, 2002). Cultures in which male offspring are more highly valued practice sex selection to ensure male offspring (ACOG Committee on Ethics, 2007). Having a son is integral to the

family in Chinese society and they regard “continuation of the family tree as a filial obligation” (Chan, et al., 2002). Cohen (2002) found both China and India had a tendency toward desiring male offspring. Even further, it was found there was an overall preference for male offspring in Latin America, Asia, Africa and the Middle East (Hill & Upchurch, 1995).

There is also the concept of family balancing to consider, in which families who have a child (or children) of one sex would like to conceive a child of the opposite sex in order to “balance” their family (Cohen, 2002; Dahl, 2005; Dawson & Trounson, 1996; Farrell, 2002; Malpani & Malpani, 2002). Dawson and Trounson (1996) define family balancing as “restoring equal representation of the genders of children in a family” (p. 2578). Other parents simply know they only want to have a boy or a girl, or even just have a preference as to what the sex of their first-born child should be (ACOG Committee on Ethics, 2007; Dahl, 2005; Dawson & Trounson, 1996; Malpani & Malpani, 2002; Robertson, 2003).

The Argument Against Nonmedical PGS

To understand why genetic research into PGS for the nonmedical purposes above should be considered unethical, it is necessary to understand the implications of its use as a sex selection tool if current research into nonmedical PGS proves to be successful and receives FDA approval. Opponents of its potential uses, once it is found to be safe and effective, cite several reasons the ability to choose the sex of a child for nonmedical reasons would be unethical.

Nonmedical PGS could result in an imbalanced male-female sex ratio based on the gender preferences of certain countries as mentioned above, as the estimated occurrence of female fetus destruction in India ranges between 2 million and 5 million per year, potentially skewing male-female sex ratios to as high as 130 males for every 100 females (Allahbadia, 2002). As a result, both India and China have banned even prenatal ultrasound testing. It has

been suggested sex selection on large scales could lead to great disparities in the population sex ratio, especially in those countries who favor male children over female children (Robertson, 2003). The American Society for Reproductive Medicine (ASRM) (2004) agrees PGS could lead to imbalanced sex ratios in certain countries (Ethics Committee of the American Society for Reproductive Medicine, 2004). In the United States, one study found 94% of men and 81% of women wanted a male as their first born child (Steinbock, 2002).

Promotion of gender discrimination is another consideration for following this line of nonmedical research. Robertson (2003) states, “Some feminists...would argue that any attention to the gender of offspring is inherently sexist” (p. 469). The Ethics Committee of the ASRM (2004) also cites gender discrimination as potential pitfall of this research, by “allowing more males to be produced as first children or by encouraging parents to pay greater attention to gender itself (p. S233). This goes hand-in-hand with the potential male-female sex ratio skew. Though sexism may not be a consideration in all countries, choosing a male offspring over a female is inherently sexist, as is choosing a female offspring over a male offspring.

Another important consideration of nonmedical PGS is its research expense. Participating in the clinical trial, whether to avoid a sex-linked disease or achieve family balance, is cost prohibitive, except to those who are financially solvent. Hollingsworth (2005) purports this inequity in access could lead to a class discrepancy based on financial status wherein those who can afford it will be able to get the most expensive and least intrusive reproductive assistance. King (2007) also acknowledges the potential for inequality of access. The expense of the technology, which is usually not covered by health insurance due to its experimental nature, promotes selective availability of nonmedical PGS based on parent financial means (Genetics and IVF Institute, 2006).

The impact of sex selection on the child and their acceptance by parents must be also be considered (King, 2007). Parents who choose the sex of their child may expect that child to behave or perform in a certain way, and parents must be prepared for this not to happen. “The unpredictability of the child produced is an intrinsic feature of human reproduction. The set of characteristics that one’s child will possess at a particular time is inherently unpredictable” (McDougall, 2005). Consider what might happen if parents asked for a boy and he turned out to be extraordinarily effeminate and not interested in sports at all (against the sexual-stereotypical norm). Or perhaps the opposite might happen - parents request a female child who turns out to be a super-athlete only interested in sports (again against the sexual-stereotypical norm). Would parents who have chosen sex-selection with a preconceived notion of their offspring in mind be able to effectively parent the unexpected?

Finally, and most frightening, is the possibility nonmedical PGS could lead to the ability to choose other genetic markers for desired traits, known as eugenics. PGD specialists are already offering this as an option. The concept of eugenics originated in ancient Greece with Plato and Aristotle who wanted to provide the most “able and effective children for the next generation” (Galton, 2005). Galton further defines eugenics as the utilization of scientific methods to achieve the best inherited components to be passed on to new generations. Attempts at eugenics are well documented, including in the World War II prison camps, as well as with sterilization of the mentally-challenged, epileptics, and the insane (actual laws in the U.S. in 1907) (Galton, 2005). Advances in technology could influence parents to begin choosing desired traits such as intelligence, athletic ability, sexual orientation, beauty, hearing, height, etc. (Henn, 2000; Hollingsworth, 2005; Robertson, 2003). Consider the recent claims of promised trait selection through PGD which have occurred within the past year – can PGS be far behind?

The Argument for Nonmedical PGS

Dahl (2003) presents the concept of “procreative liberty,” in which he implies governments should not interfere with what should be considered the rights of others, including the parental right to choose the sex of offspring. There will always be debate over what is considered right and ethical by different groups within societies. In essence, it comes down to the legislation of morality. There is also the matter of reproductive choice, solidified by *Roe v. Wade*, and the arguments against sterilization programs based on drug use (King, 2007). King also presents the great example of how government restrictions on two sickle cell carriers reproducing would never be accepted – how would it ever be possible to restrict procreation based on disease chances?

Unfortunately, gender selection does not just apply to choosing a baby’s gender in the preconception stage. One argument for the use of research to further the ability of nonmedical PGS is the level of abortion and infanticide in other countries based on knowledge of an unwanted gender. According to Allahbadia (2002), sex selection in India and China through pregnancy termination is rampant, to the point prenatal sex determination has been outlawed in both countries. Because of this, when the technology became available in India, requests for PGS became more commonplace. In China, female children in orphanages highly outnumber that of males, and the abandonment of girls shortly after birth, as well as the aborting of female fetuses, are being utilized as a method for gender selection due to the “one child” policy (Chan, et al., 2002). This begs the question of whether it is more humane and ethically right to allow research in nonmedical PGS to continue in order to alleviate the infanticide, abandonment, and abortion problems.

Some argue the concept of family balancing and its effect on the sex ratio are completely incongruent. Dahl (2005) finds it very unlikely parents will suddenly and non-proportionately start choosing boys over girls, especially in Western countries, and further that family balancing would in fact ensure a normal male-female sex ratio. The Ethics Committee of the ASRM (2004) states a couple's desire to have a child of specific gender to balance a family does not mean they expect a certain behavior from that child, and further explain some parents may understand parenting one sex is different than parenting another and desire that experience. How can a government agency deny them that opportunity when research is occurring right now with supposedly positive outcomes?

Dai (2001) presents an interesting argument from the perspective of one who was not born as the desired gender. Dai, born in Taiwan, was the second child in her family. The first born was also a girl, who Dai describes as "the beautiful first born child" (p. 37). She describes herself as "simply not a boy" (p. 37), and discusses the regret she sees in her mother's eyes, and how her mother cried for three days following her birth because she was not male. She cites herself as growing up with little self-confidence and a constant feeling of not knowing where she belonged. Her psychological suffering leads her to believe PGS could lessen the suffering of other children who are of an unwanted gender. Dai was 28 when she wrote a commentary stating, "I still feel like an outsider and an inadequate child whenever I return to Asia" (Dai, 2001).

Ethical and Regulatory Considerations

In discussing the concept of nonmedical PGS, it is important to consider already established ethical guidelines. Specifically, Beauchamp and Childress (1994) presented the four principles of bioethics as autonomy, nonmaleficence, beneficence, and justice. Autonomy is a person's ability to be his/her own person without externally imposed constraints (Christman,

2003). Beneficence is defined as the promotion of good for others through kind, merciful, and charitable acts (Beauchamp, 2008), while also seeking to prevent harm (McCormick, 1998). Nonmaleficence is described as purposefully not creating harm to or imposing unreasonable risk on others, while justice is simply providing equal treatment for all (McCormick, 1998).

Believing bioethical medical standards were disjointed because many were created from specific incidents throughout history, Emanuel et al (2000) created a “systematic and coherent framework for evaluating clinical studies that incorporated all relevant ethical considerations” (p. 2701). For example, the Nuremberg Code was created following Nazi experimental atrocities and addressed issues of informed consent and risk-benefit, but not independent review. The Declaration of Helsinki addressed the gaps in the Nuremberg Code, and The Belmont Report addressed the addition of the protection of vulnerable populations (Benedict, 2008; Emanuel, et al., 2000). After examining these and other past bioethical changes and considerations, the following seven ethical requirements for conducting ethical clinical research were proposed by Emanuel et al (2000), with the inclusion of the four basic concepts of bioethics presented by Beauchamp and Childress (1994): 1) social or scientific value; 2) scientific validity; 3) fair subject selection; 4) favorable risk-benefit ratio; 5) independent review; 6) informed consent; and 7) respect for potential and enrolled subjects. Utilizing these guidelines, the ethicality of nonmedical PGS comes into question.

Research into nonmedical PGS does not appear to satisfy the requirements of autonomy, beneficence, or nonmaleficence. The parents do make a conscious choice to participate, however it can be argued they are not really making a realistic autonomous choice. Parents’ desire and/or desperation to have a child of the gender of choice may place an external constraint on their decision-making ability. Beneficence and nonmaleficence are not evidenced as it cannot be

guaranteed nonmedical PGS is for the good of the child, and further does not harm the child based on parental expectations. Justice is questionable, not because participants are receiving unequal treatment, but because certain groups are excluded from participation (i.e. those with HIV, hepatitis, who are unmarried, or who cannot afford it).

According to Emanuel et al's (2000) seven additional bioethical guidelines, the trial cannot be shown to have social or scientific value because there is no known benefit of nonmedical PGS to society. It further cannot be established the trial is scientifically valid as resources which could be utilized to assist parents in having non-diseased offspring are being diverted to parents who want nonmedical PGS, nor is it clear whether or not nonmedical PGS is a valid scientific objective. The concept of fair subject selection is definitively not met as only those with enough financial capability can participate in the trial.

The risk-benefit ratio guideline of Emanuel et al (2000) is not met as nonmaleficence, beneficence, and nonexploitation cannot be established and the social value of nonmedical PGS is unknown; therefore, the independent review requirement cannot be established and the general ethics of the trial are in question. Valid informed consent is also questionable as autonomous decisions to participate may be overridden by intense desires for a specific gender child, which could essentially be considered coercion. Finally, without evidence of autonomy, beneficence, nonmaleficence and justice, how can there be respect for potential and enrolled subjects? In fact, disrespect is shown by simply advertising the trial as a way to balance families, which in itself is preying on desires of parents rather than furthering science.

It is interesting to note the MicroSort® informed consent document for the family balancing arm of the trial makes no mention of an actual medical benefit to participating in the trial (unless there is a history of genetic disorder):

We may benefit by participating in this study although a benefit cannot be guaranteed. We may be able to increase the likelihood of conceiving a child (or children) of the desired gender. If we have a family history of a sex-linked or sex-limited genetic disease, we may be able to prevent our child (or children) from having the disorder. Our participation in this program may provide new and useful information in medical science and may aid in the development of new techniques to help other couples select the gender of their children (MicroSort®, 2005, p. 5).

In fact, the purpose of the study itself is listed as “to evaluate the safety and effectiveness of a new technique to sort sperm to increase the likelihood of conceiving a baby of the desired gender” (MicroSort®, 2005, p. 1). Because the good of having a specific gender child for nonmedical reasons cannot be established, the informed consent document could be considered misleading to prospective parents.

There are currently no federal regulations in place in the United States specifically regarding nonmedical PGS to protect these parents (Center for Genetics and Society, 2006; Robertson, 2003). Sex selection techniques are actually promoted, making potential parents especially vulnerable. Participants in the MicroSort® clinical trial are generally protected by Title 45-Public Welfare, Part 46, Protection Of Human Subjects in the Code of Federal Regulations, as are all subjects in clinical trials; however, there are no protections specifically for those who are trying to become pregnant, whether they desire to choose the sex of their child or not (U.S. Department of Health and Human Services, 2005). The protections for pregnant women and fetuses do not extend to those attempting to get pregnant.

There are ethical guidelines regarding the practice of nonmedical PGS; however, researchers are under no obligation, other than personal, to follow them. The American College of Obstetrician and Gynecologists (2007) condemns the use of nonmedical PGS for family balancing as it is experimental and sexist, but approves it for use in preventing sex-linked

disorders. The American Society for Reproductive Medicine (ASRM) opposes sex selection, as do the International Federation of Gynecology and Obstetrics (FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health) and the United Kingdom's Human Fertilisation and Embryology Authority (HFEA), believing it to be discriminatory (King, 2007), but do not provide for protection of those who want to be parents. The HFEA has actually banned the practice of sex selection (United Kingdom's Human Fertilisation and Embryology Authority, 2007), but this has no bearing on the United States except to force couples to travel to the U.S. for the procedure. In fact, several other countries have also banned the process of nonmedical PGS, including Australia, Canada, France, Japan and India (Banerjee, 2007).

Case Examples

Cases of ethical dilemmas related to nonmedical PGS for social reasons alone are difficult to find, let alone research cases, but will increase as people realize the technology is available and join the MicroSort[®] clinical trial. Most are related to personal physician ethical standards or national regulatory standards. For example, King (2007) discusses the case of Dr. Harris, a reproductive endocrinologist, approached by a couple who only wanted to have one child, and they knew they wanted this child to be a girl. The couple had no history of fertility problems. Dr. Harris balked at the request as it was completely unrelated to medical issues, and raised the concern of physician participation in on-demand medical services, citing it could turn medical practice into merely a commercial venture. There is no mention of how this issue was resolved.

The case of Louise and Alan Masterson, a couple who lost their only daughter, involved family balancing. The couple had four sons and one daughter. Unfortunately their daughter died tragically in a fire, and in order to rebalance their family, they wanted to have another female child. Based on fears they were trying to actually replace their lost daughter, and purporting a

family made up of only sons was not to be considered unbalanced, the HFEA denied their request for sex selection and they were forced to go to Italy for the procedure (Gottlieb, 2001).

Another case involved an Australian couple who already had three sons and wanted a daughter. The couple wanted treatment in Australia, where sex selection is banned, but felt uncomfortable lying about why they needed IVF, especially since they had previously not had difficulty becoming pregnant. The couple spent \$40,000 to come to the United States for the process as it remains unregulated here (Center for Genetics and Society, 2006). In this case, there is also no mention of the outcome, although the physician who performed the procedure stated he had done so for more than 100 Australian couples (Hellard, 2007).

Conclusions

Parents desiring a child of a specific gender for nonmedical reasons are vulnerable to exploitation and discrimination by the genetic research industry. Involvement in clinical trials and use of sex selection techniques is quite expensive and available only to those who can afford it, even if it is purely for medical reasons. Though the MicroSort[®] clinical trial involves informed consent on the part of the parents, one must wonder if these parents can make an autonomous decision to participate given the dangling carrot of the possibility of family balancing. The trial does have qualifications for participation in the family balancing arm, including that couples must be married, must already have one child, and must be attempting to have a child of a different gender, but even these qualifications are discriminatory based on the justice requirement of equal treatment for all and fair subject selection. The legitimacy of researching nonmedical PGS must also be questioned as there is currently no formally established ethical or medical basis for its use (i.e., scientific value and validity). It is unknown whether nonmedical PGS is beneficial for either the child or the parents (or both), therefore, we cannot conclude

nonmedical PGS research is nonmaleficent, has social value, or presents a favorable risk-benefit ratio.

Parental preferences regarding sex selection seem to be a major impetus pushing genetic research on nonmedical PGS, however, the protections for these individuals are limited and the regulations nonexistent. Researchers in genetic sex selection must search their own souls to determine if they are researching for the greater good of people, to increase scientific knowledge, or simply for financial gain and scientific accolades. The world has seen what can happen in the pursuit of eugenics in Nazi Germany and its attempt to promote biologically superior genes, and its requirements for sterilization and elimination of those considered inferior and foreign in the population (Jewish Virtual Library, 2008). Based on world history, it is absolutely essential that consistent and ethical research guidelines be established not only to protect prospective parents, but also to protect society as a whole, hopefully ensuring eugenics does not slowly insinuate itself into science.

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